IMAGING TECHNIQUE

Computed tomography (CT Scan)





IMPORTANT NOTE

This procedure provides only the information required by Bodycad to design and manufacture personalized restorations. The procedure described in this document may differ from the procedure used for diagnostic purposes. The physician is responsible for determining whether further tests are required for diagnostic purposes.

Introduction and purpose

Through its mission, The Pursuit of Orthopaedic Perfection™, Bodycad aims to bring to market personalized restorations designed from a virtual 3D model of the patient's anatomy. The 3D model of the bone is produced by Bodycad Imager software, which employs 3D image segmentation from the patient's CT. More specifically, the present protocol provides healthcare professionals with information on scanning requirements for the capture of patient CT's of the lower extremities, for use by these algorithms.

It is important to closely follow this protocol, as this will produce a more accurate 3D model and enhance the precision of the personalized restoration. A high-quality image will provide the best results in terms of a high level of accuracy. A Bodycad representative will be on standby to answer any questions you may have and provide any additional information you may need.

Imaging techniques in this document

Scan of the joints (Hip, Knee, Ankle)

Page 4

Scan of the joints (Hip, Knee, Ankle)

Ankle

Page 4

Scan of the joints (Hip, Knee, Ankle)

Ankle

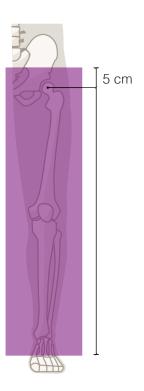
15 cm

10 cm

5 cm







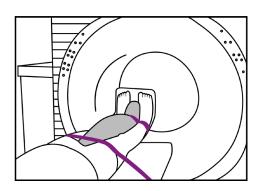
Position of the Patient

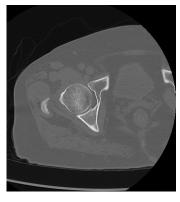
General position

- The patient must be in a supine position, with feet first (FFS) into the gantry.
- The arms are to be folded upward to the head.

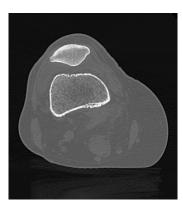
Limbs position

- The legs should be as parallel as possible to the table horizontally, without rotation.
- The knees are in full extension, without rotation.
- The patient's patellae are placed as forward as possible.
 Malrotation must be avoided by aligning the patellae halfway between the femoral condyles.
- Support may be used in order to maintain the patient in the required position.
- The patient must remain stationary.





Hip





Knee Ankle

Series to provide

- Series 1 : Full-leg scout from the hip through ankle

- Series 2 : Axial Hip, Knee, Ankle or Full leg

- Series 3 : Coronal MPR

- Series 4 : Sagittal MPR

Bilateral Scans

Unilateral images are recommended unless the patient is schedule for a bilateral procedure.

- Maximum FOV allowed for bilateral.
- If both legs cannot be captured in a FOV of 320 mm, use 500 mm FOV and reconstruct each limb individually.
- Scan both legs simultaneously.

CT scan of the joints (Hip, Knee, Ankle)

Applicable Products



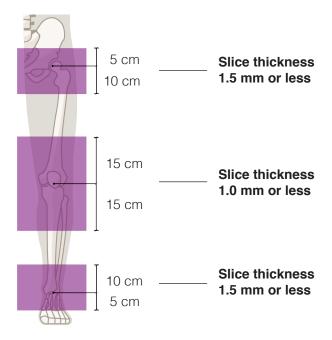


(medial unicompartmental knee system)

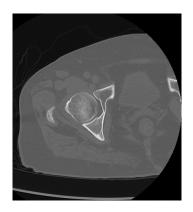
(osteotomy around the knee system)

Region of interest

- Images must be acquired from 5 cm above the center of the femoral head to 10 cm below the center of the femoral head.
- Images must be acquired from 15 cm above the knee joint to 15 cm below the knee joint (total 30 cm).
- Images must be acquired from 10 cm above ankle joint and 5 cm below the ankle joint.
- Partial skin and soft tissue must be captured along with the bone regions.

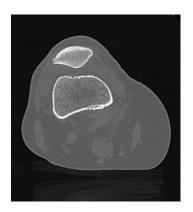


Hip region



Slice thickness	1.5 mm or smaller
Field of view	Choose the smallest possible FOV that will capture the bones of interest and partial skin and soft tissue.
Matrix	512 x 512
KVp	120 to 140 KVp
Algorithm/kernel	 Bone or Boneplus (GE) Ultra-high resolution, at least U40 or higher (Siemens) At least B60f or higher (Siemens) Other kernels that give as much high bone contrast as possible with respect to the surrounding tissue. Ensure that there is no edge enhancement.
mAs	Automatic value from the machine

Knee region



Slice thickness	1.0 mm or smaller
Field of view	Choose the smallest possible FOV that will capture the bones of interest and partial skin and soft tissue.
Matrix	512 x 512
KVp	120 to 140 KVp
Algorithm/kernel	 Bone or Boneplus (GE) Ultra-high resolution, at least U40 or higher (Siemens) At least B60f or higher (Siemens) Other kernels that give as much high bone contrast as possible with respect to the surrounding tissue. Ensure that there is no edge enhancement.
mAs	Automatic value from the machine

Ankle region



Slice thickness	1.5 mm or smaller
Field of view	Choose the smallest possible FOV that will capture the bones of interest and partial skin and soft tissue.
Matrix	512 x 512
KVp	120 to 140 KVp
Algorithm/kernel	 Bone or Boneplus (GE) Ultra-high resolution, at least U40 or higher (Siemens) At least B60f or higher (Siemens) Other kernels that give as much high bone contrast as possible with respect to the surrounding tissue. Ensure that there is no edge enhancement.
mAs	Automatic value from the machine

Full leg CT scan

Applicable Product

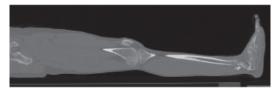


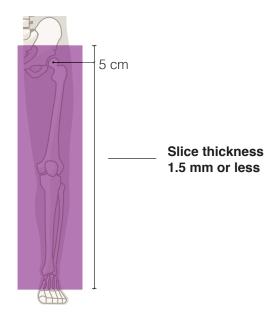
(osteotomy around the knee system)

Region of interest

- Images must be acquired from 5 cm above the center of the femoral head to the ankle and should include at least the talus. The entire foot can be included.
- Partial skin and soft tissue must be captured along with the bone regions.







Slice thickness	1.5 mm or smaller
Field of view	Choose the smallest possible FOV that will capture the bones of interest and partial skin and soft tissue.
Matrix	512 x 512
KVp	120 to 140 KVp
Algorithm/kernel	 Bone or Boneplus (GE) Ultra-high resolution, at least U40 or higher (Siemens) At least B60f or higher (Siemens) Other kernels that give as much high bone contrast as possible with respect to the surrounding tissue. Ensure that there is no edge enhancement.
mAs	Automatic value from the machine

Data anonymization and privacy

- Be sure that the required rights for transmitting data to Bodycad are respected.
- The patient name and ID must be kept in the transmitted data.
- The transmitted data will be anonymized by Bodycad before the whole process
 of personalized restoration begins. This anonymization follows the established
 Bodycad quality procedure and patient privacy guidelines.

Transmission of images

File format and instructions:

- Use only DICOM format, without lossy compression.
- Provide the images with the parameters, the scout view, additional images, notes.
- Return all images to referring physician
- Ensure that the CD or DVD is packaged appropriately in order to avoid breakage during transport.



